

labeling or otherwise affect the device shall be exempted from the premarket notification requirements of this subpart if:

- (1) The device was in commercial distribution before May 28, 1976; or
- (2) A premarket notification submission was filed by another person.

**§ 807.87 Information required in a premarket notification submission.**

Each premarket notification submission shall contain the following information:

- (a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.
- (b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.
- (c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.
- (d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.
- (e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.
- (f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.
- (g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed

for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(k) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the

original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0281)

[42 FR 42526, Aug 23, 1977, as amended at 57 FR 18066, Apr. 28, 1992; 59 FR 64295, Dec. 14, 1994]

#### **§ 807.90 Format of a premarket notification submission.**

Each premarket notification submission pursuant to this part shall be submitted in accordance with this section. Each submission shall:

(a)(1) For devices regulated by the Center for Devices and Radiological Health, be addressed to the Food and Drug Administration, Center for Devices and Radiological Health (HFZ-401), 1390 Piccard Dr., Rockville, MD 20850.

(2) For devices regulated by the Center for Biologics Evaluation and Research, be addressed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Division of Product Certification (HFB-240), 8800 Rockville Pike, Bethesda, MD 20892.

(3) All inquiries regarding a premarket notification submission should be in writing and sent to one of the addresses above.

(b) Be bound into a volume or volumes, where necessary.

(c) Be submitted in duplicate on standard size paper, including the original and two copies of the cover letter.

(d) Be submitted separately for each product the manufacturer intends to market.

(e) Designated “510(k) Notification” in the cover letter.

[42 FR 42526, Aug. 23, 1977, as amended at 53 FR 11252, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

#### **§ 807.92 Content and format of a 510(k) summary.**

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

(1) The submitter’s name, address, telephone number, a contact person, and the date the summary was prepared;

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process;

(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended.